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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/710,744	07/30/2004	David Barkalow	HVGFLM	4743
29822	7590	03/11/2005	EXAMINER	
WM. WRIGLEY JR. COMPANY RESEARCH AND DEVELOPMENT 3535 S. ASHLAND AVE. CHICAGO, IL 60609			DONOVAN, MAUREEN C	
			ART UNIT	PAPER NUMBER
			1761	

DATE MAILED: 03/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/710,744

Applicant(s)

BARKALOW ET AL.

Examiner

Maureen C Donovan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-12, 17-24 and 29-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen, WO00/42992A2 in view of Christensen, WO 93/15116 A1.

Chen discloses an edible film composition containing sweeteners, flavoring agents, softeners, emulsifying agents, active agents and film forming agents (see page 4, lines 24-33 and page 5, lines 1-3). Chen discloses using sweeteners such as sugar and dextrose, as well as using high intensity sweeteners such as aspartame (see page 10, lines 13-14). Chen discloses using flavoring agents (see page 10, lines 7-12). Chen discloses using softeners, which are called plasticizers by Chen, wherein these plasticizers include glycerin and sorbitol (see page 10, lines 20-21) and are present in the film in amounts ranging from 0.5-20% by weight of the film (see page 15, lines 4-12). Chen discloses that the film contains emulsifiers such as sorbitan esters, and that these are present in the film in amounts ranging from 0.1-10% (see page 1, lines 15-19 and page 15, lines 4-12). Chen discloses that the film contains active ingredient such as anti-plaque agents (see page 10, lines 22-33 and page 11, lines 1-12). Chen discloses using guar gum as a film forming hydrocolloid (see page 14, line 14), and that the film forming agent is present in the

film in amounts ranging from 5-99% (see page 13, lines 7-10)¹. Chen discloses that a modified starch can also be used in the film, and added to the hydrocolloid film former (see page 11, line 15), this modified starch inherently acting as a secondary film forming agent in that it adds to the composition of the film and its strength.

Chen discloses that the viscosity of the film forming agent is important in determining the properties of the resultant film, especially the dissolution time of the film (see page 13, lines 1-6 and page 24, lines 1-5). Chen also discloses examples of suitable viscosities and the properties of the films that result from using a hydrocolloid with these viscosities (see Tables 9a and 9b, pages 24-25). The viscosities as disclosed by Chen in the example are for hydroxymethylcellulose and range from 2-60cps.

Chen does not disclose using the hydrolyzed type of guar gum or the viscosity of the guar gum; nor does Chen disclose using a filler, a cooling agent or a heating agent.

Christensen teaches that in order for hydrophilic gums such as guar gum, to be useful in film-forming applications they should be low in viscosity and that non-hydrolyzed guar gum is not suitable for film forming applications since it has a high molecular weight which leads to highly viscous solutions that can not be handled in film forming processes when used in high concentrations, i.e. greater than 10% (see page 1, lines 6-14 and page 2, lines 32-35). Christensen teaches a hydrolyzed guar gum with a reduced viscosity of 8.4cps, compared to the non-hydrolyzed viscosity of 10,420 cps (see page 1, lines 4-14; page 2, lines 36-38 and page 7, Table 1).

Guar gum, heretofore, has been known in the art as a film former for orally soluble edible films, as seen in Chen and additionally as supported by Zerbe. Chen however, does not specify that the hydrolyzed type of guar gum should be used. Chen gives examples of suitable hydrocolloid viscosities to use in the films, whereas non-hydrolyzed guar gum would be much greater, as evidenced by Christensen (see Christensen, page 7, Table 1). Chen therefore recognized the importance of hydrocolloid viscosity in film forming, and would have lead one of ordinary skill in the art towards choosing a hydrocolloid of lower viscosity than guar gum. Christensen presents the same problem as the applicant, that non-hydrolyzed guar gum is too

¹ Chen recites the use of "guar gum arabic", which is interpreted to be a grammatical mistake since there is no such substance; and that the recitation was intended to be "guar gum, gum arabic" as these are known in the art as conventional film forming agents, as supported by both Zerbe, US patent number 6,177,096 and Leung, US patent number 6,596,298.

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viscous to be used at high concentrations in film forming applications (see page 1, lines 6-14). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have used the hydrolyzed guar gum of Christensen for the guar gum of Chen since Christensen presents the fact that the lower viscosity hydrophilic gums would be useful as film formers (see page 2, lines 32-35), since guar gum would be valuable as a source of dietary fiber in the films and since the hydrolyzed gum of Christensen would overcome the previously identified viscosity problem with guar gum.

2. Claims 13,14,15,16,25,26,27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen modified by Christensen as applied to claims 1-12, 17-24 and 29-35 above, and further in view of Leung, US patent number 6,596,298.

Chen modified by Christensen discloses all the features of the instantly claimed invention except for using a filler, a cooling agent or a heating agent in the film.

Leung teaches an orally soluble edible film comprised of a film forming agent such as guar gum (see Column 1, lines 8-12; Column 4, lines 64-68 and Column 5, lines 1-13). Leung teaches the use of a thickening agent in the film, such as methylcellulose, in amounts ranging from 0-20% by weight of the film (see Column 6, lines 15-18), wherein the thickening agent is interpreted to be the same as a filler as instantly claimed. Leung discloses the use of many different flavoring agents in the film, including both cooling and heating agents such as monomenthyl succinate and cinnamic aldehyde, respectively (see Column 5, lines 58-63 and Column 7, lines 35-36).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the additional ingredients as taught by Leung, in the film as disclosed by Chen as modified by Christensen since both are directed to orally soluble edible films, and since the thickening agents of Leung would perform as stated and add a thickness to the film in order to produce a film that was less flimsy and had more body to it, which would also aid in processing and packaging the films, as a more structured film would be easier to handle. Additionally the heating and cooling agents of Leung would add to the variety of film flavors and effects possible, and further provide more flavors that would appeal to the consumer.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen C Donovan whose telephone number is (571) 272-2739. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272-1398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MCD



KEITH HENDRICKS
PRIMARY EXAMINER